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V.S.

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/068,227	05/05/98	WAKI M	050237

IM52/0609

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EXAMINER	
MCCLENDON,S	
ART UNIT	PAPER NUMBER
1711	4

DATE MAILED: 06/09/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/068,227	Waki et al
Examiner	**Group Art Unit**
Sanza McClendon	1711

☒ Responsive to communication(s) filed on *May 5, 1998* .

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-20* is/are pending in the application.

Of the above, claim(s) *17 and 18* is/are withdrawn from consideration.

☒ Claim(s) *10 and 14* is/are allowed.

☒ Claim(s) *1-5, 8, 9, 12, 13, 16, and 20* is/are rejected.

☒ Claim(s) *6, 7, 11, 15, and 19* is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☒ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *3*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-16 and 19-20, drawn to photo cured hyaluronic acid gel.

Group II, claim(s) 17-18, drawn to a biomedical material kit.

2. The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the biomedical material kit does not require the photo cured hyaluronic acid gel as specified by the limitations of claims 1-16 of Group I.

3. During a telephone conversation with Louis Grubinsky on June 2, 1999 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-16 and 19-20. Affirmation of this election must be made by applicant in replying to this Office action.

Claims 17-18 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Claim Objections

5. Claims 6, 7, 11,15 and 19 are objected to under 37 CFR 1.75© as being in improper form because a multiple dependent claim cannot depend on another multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims 6, 7, 11, 15, and 19 have not been further treated on the merits.

Claim Rejections - 35 U.S.C. § 102/35 U.S.C. § 103

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 1-6, 9-10, 12- 13, and 16 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Matsuda et al (EP 0 554 898 A2).

Matsuda et al discloses a photo curable glycosaminogylcan derivative (photo curable GAG) which comprises a GAG and a photo reactive compound bound thereto and a cross linked GAG prepared by subjecting the photo curable GAG to cross linking reaction with the photo reactive compound.

Matsuda et al teaches that the GAG includes colominic acid, hydraluronic acid, and others listed on page 10 lines 35-39. These should have a molecular weight range form 4,000 to 2,000,000. This appears to read on the hydraluronic acid in the claimed invention. However, in the alternative, it would have been obvious to one of ordinary skill in the art to use hydraluronic acid with the expectation of obtaining a useful coating composition in the absence of unexpected results.

Matsuda et al teaches that the photo reactive group may be any group provided that it is capable of at least dimerizing inter-molecularly and/or intra molecularly upon exposure to light under formation of a cyclobutane ring--page 7, lines 55 to end. Matsuda et al teaches that cinnamic acid can be used as the photo reactive group among others. This appears to read on the limitations of the claimed invention. However, in the alternative, it would have been obvious to use cinnamic acid as the photo reactive cross linker as taught by Matsuda et al with the expectation of an adequately cross linked GAG in the absence of unexpected results. Matsuda et al teaches that the photo cured GAG can have a degree of substitution (DS) preferably between about 0.1 to 0.5 when used as a tissue nonadhesive material. This reads on the limitation of claim 2 and the tissue non-adhesive reads on the limitation of claim 16. Matsuda et al also teaches that when hydraluronic acid is used that the DS be between about 0.1 to 3.0. This range appears to read on the limitation of claim 2. However, in the alternative, it would have been obvious to provide a DS between about 0.1 to 0.5 as taught by Matsuda et al with the expectation of a useful tissue nonadhesive in the absence of unexpected results.

Matsuda et al teaches that the photo reactive compound (cinnamic acid) can be bound to GAG or to a spacer group. Matsuda et al teaches that the spacer groups can be basic amino acids--page 12-- and amino alcohols on page 5, line 50 with a formula* representation on page 7, line 15 when R3 is (CH2)n and n is 2. This appears to read on claim 5. However, in the alternative, it would be obvious to one of ordinary skill in the art to use a amino acid or amino alcohol spacer group as taught by Matsuda with the expectation of adequate results

in the absence of any unexpected results. Matsuda et al teaches that when basic amino acids are used as spacers the GAG is used in aqueous solution and the two are subjected to an amidation reaction in the presence of a condensing agent.

Matsuda et al teaches that the photo curable GAG is found in concentrations of amounts from 1 to 30%--page 16. This appears to read on claim 12. However, in the alternative, it would have been obvious to one of ordinary skill in the art to use concentration from 0.5 to 10% as encompassed in the concentration from about 1 to 30% with the expectation of adequate results in the absence of any unexpected results. Matsuda et al teaches that the photo curable GAG can be irradiated using UV radiation in the range of 260 to 400 nm. This appears read on the UV irradiation limitation of claim 8. In Example 1, Matsuda et al teaches that the solution of the photo curable GAG was heat sterilized before photo curing with the photo reactive group. This anticipates claim 13. In Example 12, Matsuda et al teaches that the cross linking reaction can be under heating vs. photo initiation. This anticipates claim 9.

Matsuda et al teaches that contact angles are increased as the DS is increased. And the an increase in contact angle reflects an increase in film surface hydrophobicity. It is the examiner's understanding that as the DS increases the contact angle increases and the hydrophobicity increase or i.e., the water absorption decreases. In example 15, Matsuda et al discloses swelling capacities that appear to read on the limitations of claim 3. However, in the alternative, one of ordinary skill in the art would be able to adjust the water absorption (swelling capacity) by adjusting the DS as taught by Matsuda et al to obtain a hydrophilic or

hydrophobic photo curable cross linked hydraluronic acid as taught by Matsuda et al in the absence of unexpected results.

It is the examiner's contention, that the photocrosslinked-GAG of Matsuda et al is anticipated by and/or in the alternative obvious over the claimed invention. Therefore, the photo cured cross linked-hydraluronic acid gel of Matsuda et al would inherently contain a storage modulus (G') of from 50 to 1500 Pa, a loss modulus (G'') of from 10 to 300 Pa, and a tangent delta (G''/G') of from 0.1 to 0.8 in dynamic visocelasticity measured by a rheometer under the conditions of claims 1 and 8-9. The claimed invention is read in the reference.

* It is noted that these disclosures anticipate and/or obvious over objected claims that have not been further treated on merits.

Claim Rejections - 35 U.S.C. § 103

9. Claims 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matsuda et al (EP 0 554 898 A1).

Matusda et al is disclosed in the above rejection. Matsuda et al teaches that the photo cured GAG can be used for medical applications. They can be used in various forms, such as solutions, gels, solid, etc. Matsuda et al also teaches that they can be used as controlled drug release materials. In which, they can be prepared into tablets by compression molding in, or preparing powders, granules, etc., they can be molded into films, or immobilized on

some other support, they can have ophthalmic preparation, prepared for embedding into living bodies, or prepared to be inserted in to body cavities. Matsuda et al does not expressly disclose a container in which a gel can be push out for injection. However, Matsuda et al teaches that the photo curable cross linked GAG can be made into a gel and that it can be prepared to be embedded into living bodies. Therefore, it is the examiner's contention, that it would have been obvious for one of ordinary skill in the art to use a container the can embed objects or insert object. Thus the claimed invention is read in the reference.

Allowable Subject Matter

10. Claims 10 and 14 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US Patent 5,700,848 to Soon-Shiong et al. US Patent 5,462,976 which is equivalent to EP 0 554 898 A1.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sanza McClendon whose telephone number is (703)305-0505. The examiner can normally be reached from 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jim Seidleck, can be reached at (703) 308-2462.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308 -1495.

James J. Seidleck
Supervisory Patent Examiner
Technology Center 1700

smc

June 2, 1999